

1648

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Blue, Jeffrey T.	
Serial No.:	10/030,378	Case No.: 20455P
Filed:	November 9, 2001	
For:	DETECTION OF VIRAL STABILITY	

Examiner: Le, Emily M.

Art Unit: 1648

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO RESTRICTION REQUIREMENT

Sir:

Responsive to the Restriction Requirement mailed November 5, 2003, applicants provisionally elect Group I (claims 1-8), with traverse. The restriction requirement divided the claims into two groups: Group I (claims 1-8) and Group II (claims 9-17). The examiner cites to an Assay Design description of reagents sold for a caspase-3 detection kit as a basis for finding a lack of Unity.

A common technical feature for the both groups is measuring capase 3 activity to assay virus activity. Group I claims describe measuring capase 3 activity in a method to assay for viral potency or stability. Group II claims describe measuring capase 3 activity produced from a virus in a method for identifying a stabilizing formulation.

It is respectfully submitted that the reference and arguments provided by the examiner are directed to a caspase 3 assay in general and fail to consider the use of the assay noted in the

37 C.F.R. 1.8 Certificate of Mailing

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents P.O. Box 1450 Alexandria VA 22313-1450, on the date appearing below.

MERCK & CO., INC.

BY Sheldon Heber

Date December 4, 2003

Sheldon Heber

claims. No mention is made in the Assay Design product description concerning measuring caspase 3 activity as an indication of viral activity.

The common technical feature of assaying for viral activity by measuring capase 3 activity was acknowledged in the International Preliminary Examination Report. According to the Report on page 3:

Claims 1-17 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a method for assaying the virulence of a particular virus by the employment and subsequent measurement of caspase 3.

A copy of the Report is enclosed.

The reference cited by the Examiner would not appear have any impact on Report, as the reference is merely concerned with reagents and techniques for measuring capase 3 activity. The application on page 5, lines 7-12, cites prior art references concerning reagents and techniques that can be used to measure capase 3 activity.

The comments provided above concerning a common technical feature is for Unity of Invention purposes. Such comments are not an admission that one set of claims is obvious based on another set of claims. The different claims each include additional descriptions.

Please charge deposit account 13-2755 for fees due in connection with this response. If any time extensions are needed for the timely filing of the present amendment, applicants petition for such extensions and authorize the charging of deposit account 13-2755 for the appropriate fees.

Respectfully submitted,

By Sheldon O. Heber
Sheldon O. Heber
Reg. No. 38,179
Attorney for Applicant(s)

MERCK & CO., INC.
P.O. Box 2000
Rahway, New Jersey 07065-0907
(732) 594-1958

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

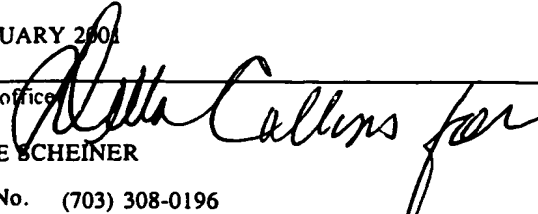
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PCT 20455	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US00/12638	International filing date (<i>day/month/year</i>) 10 MAY 2000	Priority date (<i>day/month/year</i>) 14 MAY 1999
International Patent Classification (IPC) or national classification and IPC Please See Supplemental Sheet.		
Applicant MERK & CO., INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets.
- ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
- These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 08 NOVEMBER 2000	Date of completion of this report 13 JANUARY 2001
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer  LAURIE SCHEINER
Facsimile No. (703) 305-3230	Telephone No. (703) 308-0196

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/12638

I. Basis of the report

1. With regard to the elements of the international application:*

☒ the international application as originally filed☒ the description:pages 1-12, as originally filedpages NONE, filed with the demandpages NONE, filed with the letter of _____☒ the claims:pages 13-14, as originally filedpages NONE, as amended (together with any statement) under Article 19pages NONE, filed with the demandpages NONE, filed with the letter of _____☒ the drawings:pages 1-6, as originally filedpages NONE, filed with the demandpages NONE, filed with the letter of _____☒ the sequence listing part of the description:pages NONE, as originally filedpages NONE, filed with the demandpages NONE, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).☐ the language of publication of the international application (under Rule 48.3(b)).☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in printed form.☐ filed together with the international application in computer readable form.☐ furnished subsequently to this Authority in written form.☐ furnished subsequently to this Authority in computer readable form.☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.4. ☒ The amendments have resulted in the cancellation of:☒ the description, pages NONE☒ the claims, Nos. NONE☒ the drawings, sheets/fig NONE5. ☐ This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

**Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/12638

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. statement**

Novelty (N)

Claims 1-17 YESClaims NONE NO

Inventive Step (IS)

Claims 1-17 YESClaims NONE NO

Industrial Applicability (IA)

Claims 1-17 YESClaims NONE NO**2. citations and explanations (Rule 70.7)**

Claims 1-17 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a method for assaying the virulence of a particular virus by the employment and subsequent measurement of caspase 3.

----- NEW CITATIONS -----

NONE

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/12638

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

CLASSIFICATION:

The International Patent Classification (IPC) and/or the National classification are as listed below:

IPC(7): C12Q 1/02, 1/70; G01N 33/573; A61K 49/00; A01N 63/00 and US Cl.: 435/5, 7.4, 29; 424/9.2, 93.6